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THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al. ex rel.* SANDRA GAUCH *et al.*,

Plaintiffs and Relators,

-against-

LINCARE INC. *et al.*,

Defendants.

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

-against-

LINCARE INC.,

Defendant.

18 Civ. 783 (PGG)

COMPLAINT-IN-INTERVENTION OF THE UNITED STATES

The United States of America (the "United States" or the "Government"), by its attorney, Damian Williams, the United States Attorney for the Southern District of New York, brings this action against Lincare Inc. ("Lincare" or "Defendant"), and alleges as follows:

PRELIMINARY STATEMENT

1. This is a civil fraud action brought by the United States against Lincare to recover damages and civil penalties arising from Lincare's violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, in connection with the rental of non-invasive ventilators ("NIVs") to patients covered by Medicare, Medicaid, TRICARE, the Federal Employees' Health Benefit Program ("FEHBP"), and the health insurance plan of the National Railroad Passenger Corporation d/b/a Amtrak ("Amtrak health care plan," together with Medicare, Medicaid, TRICARE, and FEHBP, the "Federal health care programs").

2. NIVs are a type of respiratory equipment designed to deliver pressurized air into the lungs of patients with respiratory failure. More specifically, NIVs help patients maintain targeted tidal volume (the volume of air inhaled and exhaled with each breath) by automatically adjusting the level of pressure support provided. Patients frequently rent NIVs for regular use in their homes. During the period of January 1, 2013, through February 29, 2020 (the "Relevant Period"), Medicare and other Federal health care programs reimbursed durable medical equipment ("DME") suppliers like Lincare as much as $1,400 per month for supplying NIV rentals to patients.

3. During the Relevant Period, Lincare knowingly submitted false claims for payment to Federal health care programs for NIV rentals: (a) when the NIVs were not medically necessary or reasonable due to the lack of continued use or continued need; (b) when Lincare did not maintain sufficient documentation to show (or otherwise verify) continued use or continued need; or (c) where Lincare approved, at the Regional Vice President-level, waivers of the

coinsurance payments that Medicare and TRICARE beneficiaries were required to pay to induce the beneficiaries to rent the NIVs based on factors other than the patient's financial need, in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(2), and Lincare's own applicable internal policies.

4. When DME suppliers like Lincare rent NIVs to Federal health care program beneficiaries and seek reimbursement for such rentals, the DME suppliers must ensure that the NIVs continue to be used and that they remain medically reasonable and necessary during the rental period. For example, under Medicare, a DME supplier is required to monitor the extent to which the beneficiary is using the NIV at home and to maintain documentation to support that the device continues to be used and is medically reasonable and necessary. In addition, DME suppliers must discontinue billing Federal health care programs when the NIV is no longer being used and is not medically reasonable and necessary.

5. Lincare, however, often continued to submit monthly claims for payments to Federal health care programs when the NIVs were no longer medically necessary or the beneficiary had stopped using the device.

6. Lincare frequently did not know, or have documentation to support, that a patient continued to use or need the NIV. Lincare nonetheless continued to seek monthly payments from Federal health care programs for these NIV rentals. Lincare's primary method to monitor patient usage of NIVs was by having their Respiratory Therapists ("RTs") conduct home visits, during which RTs would evaluate the device's settings, usage, and need for maintenance ("vent checks"). As part of the vent checks, RTs were supposed to record the extent to which patients had been using the NIVs and confirm that they were using their devices as directed by their physicians. Under Lincare's own policy, home visits were supposed to occur at least every sixty

days. However, Lincare's RTs frequently failed to comply with this policy; on tens of thousands of occasions during the Relevant Period, Lincare failed to perform home visits for NIV patients as required by its policy. Further, when RTs did conduct vent checks, they often failed to record whether, and for how many hours, patients had used their NIVs.

7. Furthermore, in some instances, Lincare continued to seek monthly payments from Federal health care programs when it was aware, through home visits and vent checks conducted by its RTs, that beneficiaries had stopped using their devices. Lincare billed for NIVs in instances when the beneficiary had not used or had very rarely used the device for over a year.

8. Finally, in violation of the AKS, Lincare's Regional Vice Presidents waived, either partially or in full, the coinsurance payment due from certain Medicare and TRICARE beneficiaries in an effort to persuade them to rent NIVs from Lincare instead of another DME supplier. These coinsurance payment waivers were not based on an individualized assessment of the beneficiaries' financial needs.

9. By engaging in the above-referenced conduct in connection with the rental of NIVs, Lincare submitted thousands of false claims to Federal health care programs in violation of the FCA and improperly obtained millions of dollars in payments.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over the Government's FCA claims pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C §§ 1331, 1345, and over the common law claims pursuant to 28 U.S.C. § 1345.

11. This Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a), which provides for nationwide service of process.

12. Further, because Defendant transacts business in this District and provides NIV rentals to patients in this District, venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b).

THE PARTIES

13. Plaintiff is the United States of America. Through its agencies, the Government administers and funds the Federal health care programs at issue in this action. More specifically, the Centers for Medicare & Medicaid Services ("CMS"), a component within the U.S. Department of Health and Human Services ("HHS"), administers the Medicare and Medicaid programs; the Defense Health Agency ("DHA") administers the TRICARE program; the U.S. Office of Personnel Management ("OPM") administers the FEHBP; and the National Railroad Passenger Corporation administers the Amtrak health care plan, which is supported by federal funding through the Department of Transportation ("DOT").

14. Lincare is a Delaware company headquartered in Clearwater, Florida. Lincare supplies DME to approximately 1.8 million patients across the United States. Defendant has approximately 700 local branches, called "Centers," throughout the United States, including branches in New York State or its surrounding areas. Through those Centers, Lincare operates its DME rental business nationwide, including, as relevant here, renting NIVs to thousands of Federal health care program beneficiaries.

15. Relator Sandra Gauch was employed by Lincare as a Sales Representative and Patient Care Representative in Illinois from approximately 2005 to 2022. Relator Michelle McNeill was employed by Lincare as a Respiratory Therapist from approximately 2011 to 2015. On or about January 29, 2018, the relators filed a complaint in the United States District Court for the Southern District of New York, under the *qui tam* provisions of the FCA, alleging, *inter*

alia, that Lincare and its affiliates billed for rentals of NIVs that were not being used by patients and offered waivers of coinsurance payments as inducements to NIV patients.

RELEVANT BACKGROUND

I. THE FALSE CLAIMS ACT AND THE ANTI-KICKBACK STATUTE

16. The FCA establishes treble damages liability to the United States for an individual who, or entity that, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B).

17. "Knowingly" is defined to include actual knowledge, reckless disregard and deliberate ignorance. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

18. The submission of a claim for payment to a Federal health care program for DME that is not reasonable and medically necessary constitutes a false claim actionable under Section 3729(a)(1)(A) of the FCA.

19. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.

20. The AKS makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, lease, order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under" federal government health care programs. 42 U.S.C. § 1320a-7b(b)(2).

21. The AKS arose out of Congressional concern that remuneration given to those who can influence health care decisions would result in goods and services being provided that are

medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect certain Federal health care programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form.

22. The AKS defines remuneration to include anything of value, including "cash" or "in-kind" payments. 42 U.S.C. § 1320a-7b(b)(2).

23. The Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, (2010) *codified at* 42 U.S.C. § 1320a-7b(g), provides that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." Accordingly, a person or entity violates the FCA when they knowingly submit or cause to be submitted claims to federal government health care programs that result from violations of the AKS.

II. THE FEDERAL HEALTH CARE PROGRAMS AT ISSUE

24. ***Medicare.*** In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426A. HHS is responsible for the administration and supervision of the Medicare program. CMS is an agency of HHS and is directly responsible for the administration of the Medicare program.

25. Medicare has several parts, including Part B, which provides coverage for outpatient medical services, including DME rentals. *See generally* 42 U.S.C. §§ 1395j–1395w-4. In pertinent part, Medicare Part B only covers services that are reasonable and necessary for the diagnosis or treatment of an illness. *See* 42 U.S.C. § 1395y(a)(1)(A). ("[N]o payment may be made under [Medicare] part A or part B for any expenses incurred for items or services . . .

which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"); 42 C.F.R. § 411.15(k)(1).

26. To assist in the administration of Part B, CMS contracts with Medicare Administrative Contractors ("MACs") to administer and pay Part B claims from the Medicare Trust Fund. *See* 42 U.S.C. §§ 1395u, 1395kk-1. MACs generally act on behalf of CMS to process and pay Part B claims and perform administrative functions on a regional level.[1] DME suppliers submit claims for payment to MACs, and, in turn, MACs process claims for Medicare beneficiaries. MACs may issue Local Coverage Determinations ("LCDs") regarding whether or not a particular item or service is covered under the "reasonable and necessary" standard. 42 U.S.C. § 1395ff(f)(2). MACs may also publish documentation, billing and coding guidance through Articles.

27. To participate in the Medicare program, DME suppliers must submit an enrollment application, Form CMS-855S, in which the DME supplier agrees to comply with Medicare program policies, instructions, and guidelines, including those issued by MACs, along with other federal laws and regulations. To be eligible for payment under Medicare Part B, DME suppliers must certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 1B of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Stature, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social [S]ecurity Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act)).

See CMS Form-855S (rev. 05/16) at 24.

[1] MACs that are awarded contracts to process DME claims are called "DME MACs."

28. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

29. During the Relevant Period, Lincare was an enrolled and participating Medicare supplier and had executed a Medicare enrollment application.

30. When Medicare beneficiaries receive DME rental items like NIVs, they typically are required to cover a portion of the cost in the form of co-insurance payments. Waiving co-insurance payments may incentivize the billing of unnecessary services.

31. ***Medicaid.*** Pursuant to the provisions of Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*, the Medicaid program was established in 1965 as a joint federal and state program created to provide financial assistance to individuals with low income to enable them to receive medical care. Under Medicaid, each state establishes its own eligibility standards, benefit packages, payment rates, and program administration rules in accordance with certain federal statutory and regulatory requirements. The states directly pay the health care providers for services rendered to Medicaid recipients, with the states obtaining the federal share of the Medicaid payment from accounts which draw on the United States Treasury. *See* 42 C.F.R. § 430.0 *et seq*. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b).

32. The majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid

federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). *See* 42 C.F.R. § 430.30.

33. Providers who participate in the Medicaid program must sign enrollment agreements with the state that certify compliance with state and federal Medicaid requirements. The agreements require, in substance, that the Medicaid providers agree to comply with all state and federal laws and Medicaid rules and regulations in connection with providing services and care to patients and billing the state Medicaid program for services or supplies furnished.

34. Medicaid providers, including DME suppliers, must also affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

35. ***Medicare and Medicaid Managed Care.*** Private insurers and managed care organizations may offer Medicare coverage to beneficiaries through Medicare Part C as Medicare Advantage Organizations ("MAOs") and may offer Medicaid benefits as Medicaid Managed Care Organizations ("MCOs"). MAOs enter into contracts with CMS under which they agree to provide Medicare benefits to beneficiaries, and MCOs contract with states to provide Medicaid benefits to beneficiaries. Pursuant to those contracts, the MAOs or MCOs are paid a capitated rate based on the number of Medicare and Medicaid beneficiaries they service and the level of sickness of those beneficiaries. DME provided to beneficiaries who receive Medicare or

Medicaid benefits through an MAO or MCO are paid for by the MAO or MCO if covered.[2] The MAO or MCO makes the initial determination, subject to appeal, as to whether the services are covered by Medicare or Medicaid.

36. ***TRICARE***. TRICARE (formerly known as CHAMPUS) is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The military health system, which is administered by DHA, is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

37. Some TRICARE options require participating members to pay a coinsurance payment and/or to meet a deductible. *See* 32 C.F.R. § 199.4(f). A provider of services generally cannot, as a matter of law, waive these coinsurance payment or deductible requirements. *See* 32 C.F.R. § 199.4(f)(9).

38. Providers of services to TRICARE beneficiaries are required to comply with TRICARE's program requirements, including its anti-abuse provisions. *See* 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(12).

[2] Any references in this Complaint to claims for payment submitted to Medicare or Medicaid, or payments made by Medicare or Medicaid, should be interpreted to include claims for payment submitted to MAOs and MCOs, or payments made by MAOs and MCOs.

39. ***FEHBP***. The Government, through OPM, administers the FEHBP. The FEHBP program provides health care benefits, including coverage of DME rental items like NIVs, for certain federal government employees and retirees as well as their family members and survivors. *See* 5 U.S.C. § 8901 *et seq*.

40. ***Amtrak***. The National Railroad Passenger Corporation (d/b/a Amtrak) is governed by Congress under 49 U.S.C. § 24101 *et seq.*, and uses federal funding to cover its capital and operating expenses, including the cost of employees' benefits. Amtrak receives federal funding through DOT to support its activities. Amtrak provides certain of its employees, retirees, and dependents with a health care plan, which provides health care benefits, including coverage of DME rental items like NIVs.

III. THE FEDERAL HEALTH CARE PROGRAMS' MEDICAL NECESSITY REQUIREMENT

41. A fundamental requirement for Federal health care programs' coverage of items and services, including DMEs, is that such are items are reasonable and medically necessary.

42. Under Medicare, for example, Congress expressly prohibited, by statute, reimbursement "for any expenses incurred for items or services . . . [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(l)(A); *see also* 42 C.F.R. §§ 411.15(k), 424.5(a)(6).

43. In the case of Medicaid, Congress expressly required each state Medicaid Plan to "safeguard against unnecessary utilization of [] care and services." 42 U.S.C. § 1396a(a)(30).

44. Pursuant to that statutory mandate, state Medicaid programs have promulgated laws and regulations to require medical necessity. New York State, for example, limits Medicaid coverage to "medical care, services, and supplies which are medically necessary and appropriate." 18 NYCRR § 500.1(b); *see also* N.Y. Soc. Serv. Law § 365-a(2) (defining Medicaid "standard coverage" to include "the cost of medically necessary medical . . . care,

services, and supplies"). The Washington Medicaid program likewise expressly conditions payment on whether "the service is medically necessary[.]" *See* WA Admin. Code § 182-502-0100(1)(b).

45. Finally, medical necessity is also a condition of coverage for items or services, including NIVs and other DME rentals, under TRICARE, FEHBP, and the Amtrak health care plan. *See, e.g.*, 32 C.F.R. § 199.4(a) (TRICARE "will pay for medically or psychologically necessary services and supplies required in the diagnosis and treatment of illness or injury").

46. Providers and suppliers are required to maintain sufficient medical records to justify the services rendered and each claim billed, including records supporting the medical necessity of the services.

47. Beyond codifying the medical necessity requirement as a basic condition of coverage, the Government also has provided guidelines and instructions to DME suppliers like Lincare regarding specific aspects of their obligations to comply with this basic requirement. Under Medicare, for example, the MACs that adjudicate DME claims have issued LCDs and Articles.

48. Specifically, Article A55426 ("Standard Documentation Requirements for All Claims Submitted to DME MACs") provided guidance to DME suppliers that they "are responsible for monitoring utilization of DMEPOS [durable medical equipment, prosthetics, orthotics and supplies] rental items[.]" The Article further explained, for "ongoing . . . rented DME items" like NIVs, the DME suppliers need to have not only "information . . . that justifies the initial provision of the item(s)," but also "information in the beneficiary's medical record to support that the item continues to remain reasonable and necessary." Finally, it reiterated that

DME suppliers "must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary."

IV. THE PROHIBITION AGAINST USING COINSURANCE PAYMENT WAIVERS AS AN INDUCEMENT

49. As noted above, the AKS prohibits the offer of remuneration to induce any person to order or lease an item or service covered by federal government health care programs. As early as 1994, the Government made it clear to providers and suppliers that the AKS's prohibition applies to offers of coinsurance payment waivers for the purpose of inducing patients to rent or purchase items or services.

50. Specifically, HHS-OIG issued a "Special Fraud Alert" to highlight that if "providers . . . or suppliers forgive financial obligations [such as coinsurance payments] for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase [or lease] items or services from them." 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994).

51. Further, while the 1994 Special Fraud Alert recognized a "hardship exception" to the "prohibition against waiving [coinsurance payments]," it also emphasized that the exception "must not be used routinely," but rather only "occasionally to address the special financial needs of a particular patient." *Id.* at 65,375.

52. In addition, the 1994 Special Fraud Alert provided a non-exhaustive list of practices that were "indicators" of "improper waivers." *See id.* As relevant here, those include promising beneficiaries that they would not be responsible for the coinsurance payment as well as waiving the coinsurance payment "for a specific group of Medicare patients for reasons unrelated to indigency." *Id.*

FACTUAL ALLEGATIONS

I. Lincare's NIV Rental Business

53. NIVs are a type of complex respiratory equipment designed to treat patients with chronic respiratory failure.

54. Due to the nature of NIV treatment as well as the nature of the respiratory conditions that NIVs are used to treat, it is generally understood that patients need to use NIVs in the manner prescribed by their physicians in order to get the full benefit of the treatment. An NIV prescription generally identifies how frequently a patient should use the device, often noting that the patient should use the NIV while they sleep at night.

55. During the Relevant Period, NIV rentals were reimbursed by Federal health care programs under specific billing codes, such as E0464 and E0466. Lincare submitted claims to federal health care programs for NIVs on a monthly basis, and received reimbursements at a rate as high as $1,400 per month.

56. CMS has classified NIVs in the "frequent and substantial servicing" category for purposes of Medicare coverage. A DME supplier like Lincare could therefore bill Medicare for an NIV rental for the machine's full-service life.

57. Starting in 2015, Lincare targeted growth of its NIV business as a strategic imperative on account of, among other things, expected reimbursement cuts by Medicare that would affect Lincare's other business lines. During the Relevant Period, Lincare dramatically increased the number of patients who rented its NIVs. A large percentage of these patients were covered by Federal health care programs.

58. In order to persuade physicians to use Lincare NIVs as opposed to a competitor's devices, the company advertised that it would offer clinical support to patients at least every

sixty days through home visits to support patient progress and ensure compliance with physicians' prescriptions.

59. Patients who are prescribed NIVs often suffer from severe respiratory illnesses. The regular monitoring of NIV patients allows a DME supplier to identify barriers to why patients are not using their devices as prescribed; to educate patients on the benefits of their prescribed treatment; to communicate with physicians to determine if modifications to patients' care plans should be made; and to ensure patients are receiving the benefits of their prescription in battling their diseases.

60. During home visits, Lincare RTs were supposed to perform clinical assessments of the patient, including by speaking with the patient about the potential therapeutic benefits of the NIV. In addition, RTs were required by Lincare to conduct vent checks, which included reviewing the device settings, determining if the device required maintenance, and documenting the extent to which the patient had been using device. Because NIVs generally record and store data relating to a patient's hours of use in an ascending manner, similar to an odometer, RTs could determine how often patients had been using their device by calculating the difference between the hours of usage the NIV showed and the hours recorded at the last vent check. Lincare relied on these vent checks to monitor patients' continued usage and need for the device.

II. Lincare Continued to Bill Federal Health Care Programs for NIV Rentals Without Confirming that Patients Still Needed and Used the Devices

61. Lincare understood that it was responsible for monitoring patients' utilization of their NIVs and that Federal health care programs require suppliers to discontinue billing NIVs that are no longer medically necessary and are no longer being used. However, in practice, Lincare often failed to verify that the monthly NIV rental claims it submitted to Federal health care programs were for NIVs that program beneficiaries continued to need and use. In some

instances, Lincare was aware that program beneficiaries had stopped using their devices for lengthy periods of time, but still continued to seek monthly payments from Federal health care programs.

62. On tens of thousands of occasions during the Relevant Period, Lincare failed to perform home visits every sixty days to verify patient NIV usage, in violation of its internal policy.

63. Many Centers lacked sufficient staff to make the required number of patient home visits. For example, in evaluating a region that had missed over 30% of its vent checks during a month, Lincare executives noted that while there were a record number of new NIVs being set up in that region, the Centers in that region were understaffed, had constant turnover, or had no staff at all.

64. On some occasions, clinical staff did not perform home visits for well over a year while Lincare continued to bill Federal health care programs.

65. As early as 2016, Lincare's Chief Operating Officer recognized that not completing vent checks "is a liability for us so we need to act fast" to implement a plan to increase compliance with Lincare's home visit policy. Yet, Lincare failed to develop and implement an adequate plan to address this failure. In 2018 and 2019, Lincare executives circulated monthly internal vent check compliance reports showing that thousands of required vent checks were not performed every month at Centers nationwide.

66. Even when RTs did visit patient homes, they often did not properly conduct vent checks and failed to take the time to record the hours of NIV usage. For example, in one region, RTs would rush through the visit, often just making sure the machine was still there and that the

settings were the same as the last visit. Some RTs received little to no training on how to adequately perform a vent check and did not know what was required of them.

67. In a July 21, 2022 deposition, the Chief Compliance Officer acknowledged that RTs in a certain region "weren't doing … a true clinical assessment of the patient." Patients were often not educated about the potential therapeutic benefits of the NIVs, and their physicians were often not informed about how the patients were using the device such that they could modify care plans, if needed. In January 2019, the Chief Compliance Officer stated in an internal email that in that region, "clinicians had no clue whether the patients were compliant or not."

68. In addition, Lincare had the ability to remotely monitor patients' NIV usage for certain newer NIV models through online cloud-based platforms offered by the device's manufacturer. These platforms allowed DME suppliers to view clinical data, including hours of usage and trends, online. However, during the Relevant Period, Lincare did not take advantage of these online tools to confirm that patients were using the devices as directed.

69. As result of the missed or improperly performed RT visits and the failure to remotely monitor patients' NIV usage, Lincare frequently lacked data or information regarding whether many of its NIV patients—including Federal health care program beneficiaries—continued to need and use their NIVs. Yet, Lincare continued to seek monthly payments from Federal health care programs for these NIV rentals. For example:

- Patient A, a Medicare beneficiary, received a NIV rental from Lincare in July 2017. Over the course of the next two- and-a-half years, Lincare's RTs did not conduct any home visits to verify that Patient A still needed and was using the device. Further, a 2018 audit conducted by Lincare found that it was "unknown" whether Patient A consistently used the NIV. Nonetheless, from July 2017 through the end of the Relevant Time Period, Lincare submitted monthly claims for payment for the NIV rental.
- Patient B, a Medicaid beneficiary, received a NIV rental from Lincare in April 2015. After performing a vent check in November 2015 that showed approximately eleven hours of total of use since April 2015, Lincare's RTs did

not verify that Patient B still needed and was using the device. Nevertheless, from November 2015 through December 2018, Lincare continued to submit monthly claims for payment for the NIV rental.

70. When Lincare's RTs were able to visit NIV patients, they found in many cases that patients had stopped using their NIVs or had barely used their NIVs over an extremely extended period of time. Although Lincare's executives knew that billing should be discontinued in such cases, branch office employees and billing staff often did not take steps to stop seeking payments from Federal health care programs or to determine if the NIV rentals were still medically necessary.

71. Lincare management was aware that the company continued to bill for NIV rentals provided to patients who were not using their NIVs or were using them in only a *de minimis* manner. Lincare's own internal audits revealed this. For example, an internal audit conducted in 2018 revealed that only 10 of 56 NIV patients in one Center had consistently used their NIVs. With respect to one patient, the audit report noted "we have been billing Medicare every month since 7/2/15 and Pt. has hardly used it all this time." Lincare's National Healthcare Services Manager also sent internal emails to other Lincare executives noting that many patients had reported to Lincare that they were using their NIVs "0 hours per day." And as one Regional Vice President stated in an internal email in 2017, "How do we in good conscious [sic] think this is ok for a patient to use a vent less than 1 hr a day?"

72. Lincare frequently continued to bill Federal health care programs even after it had information indicating that program beneficiaries had stopped using their NIVs. For example:

- Patient C, a Medicare beneficiary, received a NIV rental (a Trilogy branded NIV) from Lincare in November 2016. After a vent check noted that he had used the ventilator for just 40 hours over four months, Patient C stopped using the NIV entirely between July 2017 until May 2019. According to Lincare's records, a physician noted during this period that the patient was "not a candidate for Trilogy as treatment worsens stomach disorder" and that Patient C had stopped

using the NIV. Nevertheless, Lincare continued to submit monthly claims for payment for the NIV rental through the end of May 2019.

- Patient D, a Medicare beneficiary, received a NIV rental from Lincare in March 2016. Lincare vent check documents reflect that Patient D used his NIV for fewer than a total of two hours from July 2016 to May 2018. Nonetheless, Lincare continued to submit monthly claims for payment for the NIV rental from July 2016 through the end of 2017, and for the month of May 2018.
- Patient E, a Medicare beneficiary, received a NIV rental from Lincare in August 2016. Documents from vent checks performed through April 2017 do not reflect any evidence of usage, and the device was removed from the patient's home in July 2017. However, Lincare continued to submit monthly claims for payment for the NIV rental through November 2018.

III. Lincare Offered Coinsurance Payment Waivers to Induce Medicare and TRICARE Beneficiaries to Rent NIVs from Lincare

73. Some Federal health care program beneficiaries who receive NIV rentals, including Medicare and TRICARE beneficiaries, may be required to cover a certain portion of the payment for the NIV in the form of a coinsurance payment (typically 20% of the monthly reimbursement rate for Medicare beneficiaries).

74. Coinsurance payments, like deductibles, give patients an incentive to choose the most cost-effective therapy and are intended to avoid the billing of unnecessary services. As HHS-OIG observed in its 1994 Special Fraud Alert, "[s]tudies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free." 59 Fed. Reg. at 65,375.

75. The waiver of coinsurance payments may violate the AKS if, among other things, the coinsurance payments are waived knowingly and willfully to induce an individual to lease an item or service that is payable by a health care program defined under 42 U.S.C. § 1320a-7b.

76. During the Relevant Period, there were instances when Lincare offered to waive NIV coinsurance payments to induce Medicare and TRICARE beneficiaries to rent Lincare NIV

devices. For example, one of Lincare's Regional Vice Presidents ("RVPs") authorized Center managers to offer to waive coinsurance payments to persuade patients to rent NIVs without assessing the beneficiary's financial need or ability to make all or some of the payment.

77. One RVP ("RVP 1") told Lincare's Chief Operating Officer that their practice was to negotiate "every" co-insurance payment when a patient says they "cannot or will not pay." RVP 1 also told a Center manager that he could approve full coinsurance waivers "so don't lose a pt over money."

78. At times, Lincare approved total coinsurance waivers in order to protect revenue streams. For example, after a patient had initially been approved for a 70% coinsurance payment waiver, RVP 1 granted a 100% waiver instead after a Center manager explained that Lincare would still receive significant revenue per month if the coinsurance payment was completely written off and that the patient came from an important referral source.

79. This conduct also violated Lincare's Coinsurance Sales Accommodation Waiver Policy, which prohibited the waiver of coinsurance payments for Medicare and TRICARE beneficiaries for reasons unrelated to the patient's financial ability to make the payment, including for reasons like inducing patients to seek care from Lincare.

* * *

80. As result of the above-referenced improper practices, Lincare submitted thousands of false claims to Federal health care programs in violation of the FCA and improperly obtained millions of dollars in payments.

FIRST CLAIM

Violations of the False Claims Act: Presenting False Claims for Payment

(31 U.S.C. § 3729(a)(1)(A))

81. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

82. The Government asserts claims against Lincare under 31 U.S.C. § 3729(a)(1)(A).

83. As a result of its improper practices set forth above in connection with the rental of NIVs to Federal health care program beneficiaries, Lincare knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

84. Defendant presented or caused to be presented these claims with actual knowledge of their falsity, or in deliberate ignorance or reckless disregard of whether or not they were false.

85. If the Federal health care programs had been fully aware of Lincare's improper practices alleged above, those programs would not have paid the Lincare NIV rental claims at issue.

86. By reason of these false or fraudulent NIV rental claims, the Government has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND CLAIM

Violations of the False Claims Act: Use of False Statements

(31 U.S.C. § 3729(a)(1)(B))

87. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

88. The Government asserts claims against Lincare under 31 U.S.C. § 3729(a)(1)(B).

89. As a result of its improper practices set forth above in connection with the rental of NIVs to Federal health care program beneficiaries, Lincare made and used, or caused to be made and used, false records and statements that were material to the payment of false or fraudulent claims by Federal health care programs in violation of 31 U.S.C. § 3729(a)(1)(B). These false records and statements included but are not limited to false statements regarding the medical necessity of certain NIV rentals and false certifications that the claims complied with applicable laws, regulations, and program instructions.

90. If the Federal health care programs had been fully aware of the falsity of the records or statements that Lincare made and used, or caused to be made and used, those programs would not have paid the Lincare NIV rental claims at issue.

91. By reason of the false records or statements, the Government has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for violation.

THIRD CLAIM

Payment by Mistake of Fact

92. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

93. The Government seeks relief against Lincare to recover monies paid under mistake of fact.

94. The Government paid claims for NIV rentals for Federal health care program beneficiaries based on the mistaken and erroneous belief that the devices were reasonable and medically necessary, and that the claims were not the result of coinsurance payment waivers to

induce patient rentals in violation of the AKS. These erroneous beliefs were material to the determination to pay for the claims submitted.

95. By reason of the foregoing, the Government has been damaged in a substantial amount to be determined at trial.

FOURTH CLAIM

Unjust Enrichment

96. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

97. As a result of its improper practices set forth above in connection with the rental of NIVs to Federal health care program beneficiaries, Lincare has received payments to which it was not entitled and therefore was unjustly enriched. The circumstances of these payments are such that, in equity and good conscience, Lincare should not retain those payments, the amount of which is to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the Government respectfully requests that judgment be entered in its favor against Lincare as follows:

(a) On the First and Second Claims (FCA violations), for a sum equal to treble damages and civil penalties to the maximum amount allowed by law;

(b) On the Third and Fourth Claims (Payment by Mistake of Fact and Unjust Enrichment), a sum equal to damages to the extent allowed by law; and

(c) Granting the Government costs and such further relief as the Court may deem proper.

Dated: New York, New York
February 8, 2024

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